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Internal Audits: ISO 13485 conformity assessment

Elevate Medical Quality with ISO 13485 excellence

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Benefits of working with a quality system under ISO 13485

- **Allows the certification of medical devices under the CE Marking**
- **High credibility of your company**
- **Great competitive advantage**
- **Increased customer satisfaction**
- **Protection against legal proceedings**

Who needs to comply with the ISO 13485 standard?

- Manufacturers of medical devices
- Distributors of medical devices
- Importers of medical devices
- Sterilization services for medical devices
- Technical assistance and maintenance services
- Authorized representatives of medical devices

Why is it necessary to carry out internal audits of the quality system under ISO 13485?

1. Regulatory Compliance: Conducting conformity assessment ensures that a company's QMS alings with these regulatory requirements.

2. Product Quality: Implementing and assessing conformity to these standards enhances product quality, leading to greater customer satisfaction, fewer product recalls, and improved brans reputation.

3. Legal and Liability Protection: ISO 13485 Conformity Assessment is vital for medical device companies to meet regulatory requirements, ensure patient safety, maintain product quality, manage risks, access global markets, foster improvement, and protect against legal and liability issues.

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How is the audit process is carried out?

Top 5 non-conformities, as presented:

Number 1 - ISO 13485 Clause 7.1 - Planning of product realizaion including risk management.

- Issue #1: Records of risk management not updated during life cycle of product.
- Issue #2: PMS data not feeding into Risk Management & Clinical Evaluation.
- Issue #3: Risk management process not aligned to ISO 14971:2019, including applicable Annex (e.g. ZA/ZB for EU Regs).
- Issue #4: No risk management process in place.

Key takeaway: Must ensure that you establish robust links to change management, PMS, and design inputs.

Number 2 - ISO 13485 Clause 8.2.4 - Internal audit

- Issue #1: Records of internal audits not complete (reports, plans, CAPAs).
- Issue #2: Risk-based approach not applied to planning of audits or Internal audits schedule not maintained.
- Issue #3: No timely follow-up of actions resulting from internal audits.
- Issue #4: No records of internal auditor competence to applicable regulation(s).
- Issue #5: Internal auditor not impartial.

Key takeaway: Must ensure that you can show evidence of a risk-based approach to internal audits, covering regulatory requirements, by trained auditors, and with timely follow-up.

Number 3 - ISO 13485 Clause 7.5.6 - Validation of processes for production and service provision.

- Issue #1: Records of process validation and production software validation not maintained.
- Issue #2: Re-validation process not defined.
- Issue #3: Not utilising a risk-based approach or defining statistical techniques/sample size rationales in validation activities.
- Issue #4: No demonstrable links to change management process.
- Issue #5: Equipment qualification records not held (specially installation and operational qualification for new equipment).

Key takeaway: Must ensure that you can demostrate robust process links to change and risk management processes.

Number 4 - ISO 13485 Clause 8.2.6 - Monitoring and measurement of product

- Issue #1: Test/verification records not maintained.
- Issue #2: Acceptance criteria not defined or not aligned with design specification.
- Issue #3: Traceability to individuals performing tests.
- Issue #4: Monitoring and measuring of product process not defined & no demostrable link to non-conforming product process.

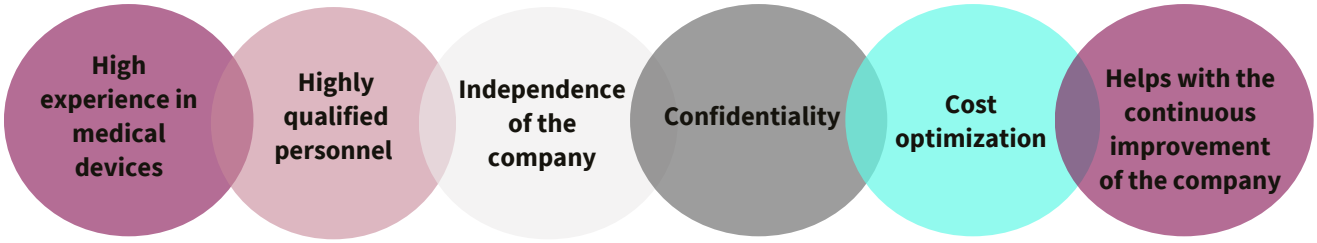
Key takeaway: Must ensure that you have adequate monitoring and measuring for product conformity during manufacture and its conformity to design specification.

Number 5 - ISO 13485 Clause 7.5.1 - Control of production and service provision

- Issue #1: Incomplete or insufficiently completed barch release/production records.
- Issue #2: Inadequate monitoring and measuring during manufacturing process.
- Issue #3: No records of qualification of infrastucture.
- Issue #4: Insufficient documentation to ensure product conformity to specification.

Key takeaway: Must ensure that you show sufficient control and records to demonstrate conformity to specification.

Reasons to outsource internal audits with Asphalion



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WHY WORK WITH US?

- **Multidisciplinary team: clinical & regulatory affairs and quality assurance**
- **Pragmatic approach to guide medtech developers**
- **Experience with a wide variety of medical technologies**
- **Flexible collaboration model for start-ups, SMEs and large companies**
- **Optimization of Time to Market**
- **Tailored services**

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